Patent
Attorney's Docket No. 033172-001



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | |
|---|---|---|
| In re Patent Application of | ) | |
| | ) | |
| Elisabeth WOLPERT et al. | ) | Group Art Unit: 1635 |
| | ) | |
| Application No.: 09/319,736 | ) | Examiner: K. Lacourciere |
| | ) | |
| Filed: August 2, 1999 | ) | |
| | ) | |
| For: THERAPEUTIC APPLICATIONS OF ANTIGENS OR EPITOPES ASSOCIATED WITH IMPAIRED CELLULAR PEPTIDE PROCESSING E.G. EXPRESSED ON RMA-S CELLS TRANSFECTED WITH A B7-1 GENE | ) | |

**RESPONSE TO RESTRICTION REQUIREMENT TRANSMITTAL LETTER**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Enclosed is a Response to Restriction Requirement for the above-identified patent application.

[X] A Petition for Extension of Time is also enclosed.

[ ] A Terminal Disclaimer and a check for [ ] $55.00 (248) [ ] $110.00 (148) to cover the requisite Government fee are also enclosed.

[ ] Also enclosed is _____ .

[X] Small entity status is hereby claimed.

[ ] Applicant(s) request continued examination under 37 C.F.R. § 1.114 and enclose the [ ] $370.00 (279) [ ] $740.00 (179) fee due under 37 C.F.R. § 1.17(e).

[ ] Applicant(s) previously submitted ___, on ___, for which continued examination is requested.

[ ] Applicant(s) request suspension of action by the Office until at least _, which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R. § 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.

[ ] A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (146/246) is also enclosed.

[X] No additional claim fee is required.

[ ] An additional claim fee is required, and is calculated as shown below:

| AMENDED CLAIMS | | | | | |
|---|---|---|---|---|---|
| | NO. OF CLAIMS | HIGHEST NO. OF CLAIMS PREVIOUSLY PAID FOR | EXTRA CLAIMS | RATE | ADDT'L FEE |
| Total Claims | | MINUS = | | × $18.00 (103) = | -0- |
| Independent Claims | | MINUS = | | × $84.00 (102) = | -0- |
| If Amendment adds multiple dependent claims, add $280.00 (104) | | | | | |
| Total Amendment Fee | | | | | |
| If small entity status is claimed, subtract 50% of Total Amendment Fee | | | | | |
| TOTAL ADDITIONAL FEE DUE FOR THIS AMENDMENT | | | | | -0- |

[ ] A claim fee in the amount of $_____ is enclosed.

[ ] Charge $_____ to Deposit Account No. 02-4800.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____
Dawn M. Gardner
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Date: January 14, 2002

#17
KP
1-22-02

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| Filed: August 2, 1999 | ) | |
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| For: THERAPEUTIC APPLICATIONS OF ANTIGENS OR EPITOPES ASSOCIATED WITH IMPAIRED CELLULAR PEPTIDE PROCESSING, E.G. EXPRESSED... | ) | |

## RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In complete response to the Official Action (a Restriction Requirement) dated August 14, 2001, applicants offer the following remarks.

In the Restriction Requirement, the claims of the instant invention were divided into the following groups of invention:

Group I: Claims 13-24, 115-117 and 132-133, drawn to an isolated antigen or epitope, a method of making said antigen or epitope and a method of using said antigen or epitope.

Group II: Claims 25 and 26, drawn to a nucleic acid encoding an antigen or epitope.

Group III: Claims 16 and 27, drawn to a method of preparing a pharmaceutical composition comprising a nucleic acid encoding an antigen or epitope.

Group IV: Claims 28 and 29, drawn to a method of treatment using a pharmaceutical composition comprising a nucleic acid encoding an antigen or epitope.

Group V: Claims 30-32, drawn to a method of eliciting or stimulating immunological effector cells by contacting effector cells with antigens or epitopes.

Group VI: Claims 33-47, drawn to a method of preparing a pharmaceutical agent or vaccine.

Group VII: Claims 48-57, drawn to a method of treatment by administering cells to a patient.

Group VIII: Claims 58-63 and 117-123, drawn to a method of treatment comprising removal and treatment of cells from a patient.

Group IX: Claims 65-68 and 134-137, drawn to a pharmaceutical composition comprising an agent that inhibits cellular peptide processing for MHC presentation.

Group X: Claims 65-70 and 138-139, drawn to a nucleotide sequence encoding an agent that inhibits cellular peptide processing.

Group XI: Claims 65-68, 71-73 and 140-142, drawn to a nucleotide sequence complementary to a sequence coding a component that takes part in cellular peptide processing.

Group XII: Claims 74, 76 and 77, drawn to a method of treatment using a pharmaceutical composition comprising an agent that inhibits cellular peptide processing for MHC presentation.

Group XIII: Claims 74-79 and 124, drawn to a method of treatment using a nucleotide sequence encoding an agent that inhibits cellular peptide processing.

Group XIV: Claims 74-77, 80-82 and 125-127, drawn to a method of treatment using a nucleotide sequence complementary to a sequence encoding a component that takes part in cellular peptide processing.

Group XV: Claims 83-104, drawn to a method of eliciting or stimulating effector cells by contacting effector cells with cells expressing antigens or epitopes.

Group XVI: Claims 105-110 and 129-131, drawn to a pharmaceutical composition comprising cells specific for antigens or epitopes.

Group XVII: Claim 111, drawn to a method of making a pharmaceutical composition comprising cells specific for antigens or epitopes.

Group XVIII: Claims 112 and 113, drawn to a pharmaceutical composition comprising cells expressing endogenous antigens or epitopes associated with impaired cellular peptide processing.

Group XIX: Claim 114, drawn to a method of making a pharmaceutical composition comprising cells expressing endogenous antigens or epitopes associated with impaired cellular peptide processing.

Group XX: Claim 128, drawn to a method of inducing expression of antigens or epitopes in cells.

Applicants hereby elect the Group XV invention, drawn to claims 83-104, with traverse.

The Examiner purports that the above recited groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1. Applicants respectfully disagree, and believe that each of the groups of inventions are sufficiently linked so as to form a single general inventive concept.

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. M.P.E.P. § 1893.03(d). If an application contains more than one invention, applicants have the right to include in a single application those inventions which are so linked as to form a single general inventive concept. Further, a group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The special technical feature is what defines the contribution which each claimed invention, considered as a whole, makes over the prior art. M.P.E.P. § 1893.03(d). Applicants submit that the technical feature which forms the special technical relationship among the inventions of the present application are the isolated epitopes or antigens associated with impaired peptide processing of the claims of Group I.

The Examiner purports that Sanda et al disclose antigens or epitopes associated with impaired cellular peptide processing, and therefore the subject matter of claim 13 is not free of the prior art. Applicants respectfully disagree. Sanda et al does not disclose or

suggest isolated epitopes or antigens associated with impaired peptide processing. These isolated epitopes or antigens associated with impaired peptide processing are normally expressed on target cells in which cellular peptide processing for MHC presentation is impaired. Applicants have identified these epitopes or antigens and have isolated them from the target cells on which they are normally expressed. When these epitopes or antigens are expressed on the target cells, recognition of said target cells by T-lymphocytes may be increased if peptide processing for MHC presentation on said target cell is decreased. Since Sanda et al does not disclose or suggest the isolated epitopes or antigens of claim 13, Sanda et al does not render obvious the invention of claim 13. Therefore, the subject matter of claim 13 is free of the prior art and as such a special technical feature does link the claims of the instant application, i.e. the isolated epitopes or antigens of claim 13.

In light of the above, withdrawal of the requirement for restriction between Groups I-XX is respectfully requested. Such action is believed to be in order.

At the very least, modification of the Restriction Requirement is respectfully requested and believed to be in order. Applicants suggest the following Groups of claims for Restriction, if Restriction is deemed necessary.

Group AI: Claims 13-29, 30-32 and 132-133, drawn to isolated antigens or epitopes associated with impaired peptide processing, methods for eliciting or stimulating immunological effectors (i.e. T-cells) against the isolated antigens or epitopes associated with impaired peptide processing, and kits comprising antigens or epitopes associated with impaired peptide processing.

Group AII: Claims 83-104, 112-114, 115-127, 129-131 and 134-142, drawn to methods of eliciting or stimulating effector cells by contacting effector cells with cells expressing antigens or epitopes; pharmaceutical compositions or vaccines, and methods of making pharmaceutical compositions, comprising cells expressing endogenous antigens or epitopes associated with impaired cellular peptide processing; methods of treatment comprising administering to a patient cells expressing endogenous epitopes or antigens associated with impaired peptide processing, together with a pharmaceutically acceptable carrier or diluent; kits comprising cells expressing endogenous epitopes of antigens associated with impaired peptide processing to be used for stimulating T-cells against epitopes or antigens associated with impaired peptide processing; and kits for use in stimulating immunological effectors other than T-cells.

Group AIII: Claims 49-57 and 105-111, drawn to methods of treatment comprising administering to a patient cells or molecules specific for antigens or epitopes associated with impaired cellular peptide processing; and pharmaceutical compositions or vaccines comprising cells or molecules directed against antigens or epitopes associated with impaired cellular peptide processing.

Group AIV: Claims 33-47, 65-73 and 74-82, drawn to methods for preparing a pharmacological agent or vaccine; a pharmacological composition or vaccine comprising T-cell stimulatory agents or a gene encoding such agents; and method of treatment comprising administering to a patient T-cell stimulatory agents or genes encoding such agents.

Group AV: Claims 58-63, drawn to methods of treatment comprising removal and treatment of cells from a patient.

If the Examiner agrees to the modification of the Groupings, applicants hereby elect the claims of Group AII, claims 83-104, 112-114, 115-127, 129-131 and 134-142.

Early and favorable action in the form of a Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney so that prosecution would be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____
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